



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

CD

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,526	12/05/2001	Richard J. Massey	100390-6370	3441
35745	7590	06/17/2004	EXAMINER	
KRAMER LEVIN NAFTALIS & FRANKEL LLP INTELLECTUAL PROPERTY DEPARTMENT 919 THIRD AVENUE NEW YORK, NY 10022			CEPERLEY, MARY	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/007,526	MASSEY ET AL.
	Examiner	Art Unit
	Mary (Molly) E. Ceperley	1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 19-38 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 19-38 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

1) Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

2) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4) Claims 19-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no description in the specification of the claim 19 terms "substance" and "electrochemiluminescence co-reactant". There is also no description of the "compositions" and "kit" of claims 29-36.

5) Claims 19-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific configurations of a nanotube to which an ECL label and enzyme substrate are attached (see pages 78, 80, 85 and 97-100 of the specification and Figs. 3, 10 and 11), does not reasonably provide enablement for a nanotube, "co-reactant" and ECL label attached in any other configurations. In order for the disclosed enzyme/enzyme substrate reaction to be detected by the ECL label, the reactive components on the nanotube must be configured consistent with the requirements described in the specification including specific distances and types of attachment between components.

Art Unit: 1641

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

6) Claims 19-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) In claim 19, it is unclear what is meant by the terms "substance" and "electrochemiluminescence co-reactant" which are undefined in the specification. Other than containing "a carbon nanotube", it is unclear what the nature and function of the remainder of the "substance" are. In the absence of the recitation of the specific type of reaction which is to be undergone by the "substance", the nature of the "co-reactant" cannot be determined.

b) Claim 19 is indefinite and incomplete for the reason that the relative configuration of the "nanotube", "electrochemiluminescence co-reactant" and "electrochemiluminescent label" components cannot be determined.

c) In claims 28 and 29, it is unclear what is meant by the term "substrate". This generic term includes, for example, a solid phase such as polystyrene.

d) For claim 28, the nature of the "enzyme and/or substrate" as it relates to the "substance" is unclear. Further, it is unclear how the "enzyme and/or substrate" is configured relative to the "substance"; for example, it is unclear if the "enzyme and/or substrate" is attached to the "substance" or if it is present as a separate component in the "composition".

e) Claims 37 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: **(i)** any requirement for a reaction between the "analyte" and a component of the "composition" which would trigger an ECL response and **(ii)** a step which correlates the ECL detection with the "presence or amount of analyte in the sample".

Art Unit: 1641

f) In claim 38, it is unclear how the additional ("further comprises") "enzyme" or "enzyme substrate" functions in the context of the method of independent claim 37.

7) The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8) Claims 19-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,866,434. Although the conflicting claims are not identical, they are not patentably distinct from each other because the composition of instant claim 19 comprised of "a carbon nanotube" with attached "electrochemiluminescence co-reactant" and "electrochemiluminescent label" and the assays which use this composition are clearly inclusive of the compositions and assays of the claims of the patent. Compare, for example, the composition of instant claim 19 and claim 18 of the patent which comprises a "graphitic nanotube" linked to both "an electrochemiluminescent label" and an "enzyme" (a "co-reactant").

Art Unit: 1641

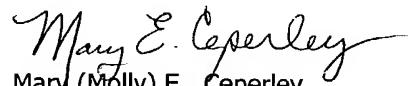
9) Claims 19-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-35 of U.S. Patent No. 6,362,011. Although the conflicting claims are not identical, they are not patentably distinct from each other because the composition of instant claim 19 comprised of "a carbon nanotube" with attached "electrochemiluminescence co-reactant" and "electrochemiluminescent label" and the assays which use this composition are clearly inclusive of the compositions and assays of the claims of the patent. Compare, for example, the composition of instant claim 19 and claim 5 of the patent which comprises a "graphitic nanotube" linked to both "an electrochemiluminescence label compound" and an "assay performance substance" (a "co-reactant").

10) An inquiry of a general nature which is not related to the prosecution on the merits should be directed to Technology Center 1600 telephone number (571) 272-1600. The general fax number for the USPTO is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823.

June 15, 2004


Mary (Molly) E. Ceperley
Primary Examiner
Art Unit 1641